Life Sciences M&A

An in-house lawyer's perspective

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NOVARTIS

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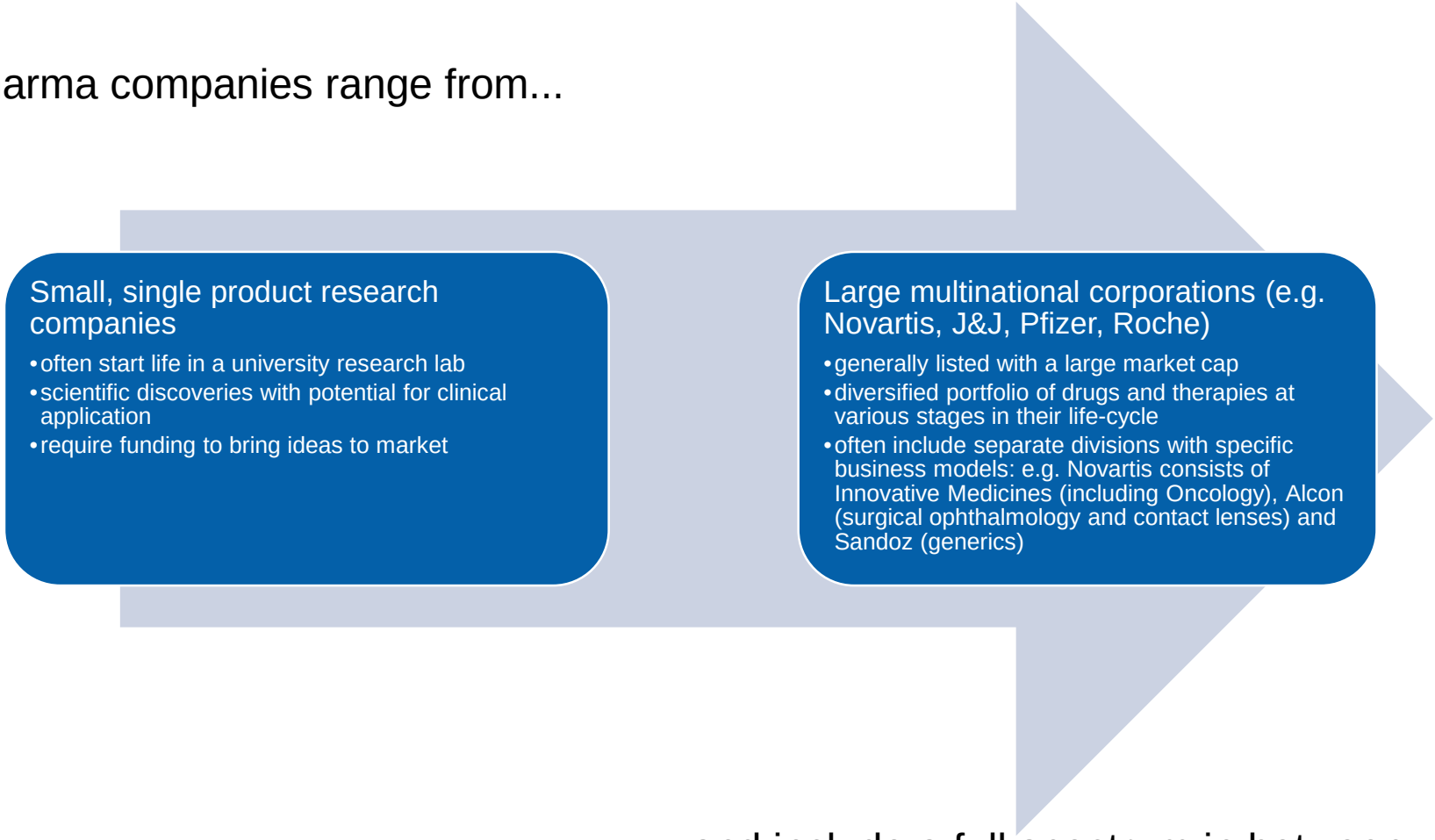
About me

- English qualified solicitor
- Worked at Hogan Lovells from 2006 to 2016
  - Based in London
  - Secondments in Moscow, Hong Kong, Ulaanbaatar
  - Client secondment to Novartis AG, June 2014 – March 2015
- Joined Novartis as in-house counsel, March 2016
  - Based in Basel, Switzerland
  - Work in the Group M&A Legal team
  - Transactions run out of Basel but with a global scope

The “life sciences industry” includes a wide range of companies...

Pharma companies range from...



...and include a full spectrum in between

...with the common underlying aim of producing medicines for patients

- Novartis states its purpose as follows:
  - *At Novartis, **our mission is to discover new ways to improve and extend people's lives**. We use science-based innovation to address some of society's most challenging healthcare issues. We discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible*
- In meeting the aim of helping patients, there are a number of challenges which all pharma companies face:
  - Extended life expectancy puts an increased burden on health systems, leading to **pricing pressure** on drugs
  - Drug **development is a long, expensive and uncertain** process
  - Approvals must be obtained and managed on a jurisdiction by jurisdiction basis
  - Innovator companies face **constant pressure from competitors and generic manufacturers**

A “big pharma” company is a complex organization…

...that relies on new products and innovation for continued growth

- **Innovative products drive growth** for life sciences companies
- Continuous **in-house R&D efforts** to make the next blockbuster discover
- However, in-house **R&D is lengthy and costly** – up to 10 years to take a new product to market, at an industry average cost of $2.5 billion
- As a result, Evaluate Pharma report that of the **top 50 selling drugs in 2014 only 4 were developed in-house**
- Therefore, **pharma companies rely on M&A / in-licensing / other transactions with third parties** to complement in-house R&D

Life sciences transactions encompass a wide range of transactions...

Early stage investments	Venture capital / private equity style investments into start up or early stage biopharma companies
In / Out Licensing	Licensing IP rights for use in product development (usually in return for royalty payments)
Collaboration agreements	Arrangements between companies to collaborate on the development of a product (e.g. a combination therapy)
Joint ventures	Corporate joint ventures to combine specific portfolios of drugs held by separate pharma companies (e.g. Novartis/GSK – OTC, GSK/Pfizer - HIV)
Product acquisitions	Acquisitions of single products (or a portfolio of products) either in-development or marketed
Company acquisitions	Acquisitions of companies with a portfolio of products (in-development or on the market)
"Mega" mergers	High value combinations of companies with large portfolios of marketed products

...but the issues that are at the heart of transactions are common

- Complex **milestone/earn-out structures** are often required
- **IP is a key value driver** and proper due diligence is key
- **Antitrust issues are common and often complex** and require sector specific knowledge
- Regulatory transfers need to be addressed on a country-by-country basis
- **Tech transfers can be lengthy** and require robust interim supply/services agreements
- The need to **retain key scientists** behind novel developments

Earn-out provisions are a frequent source of negotiation...

- Many life sciences transactions will include earn-out provisions – these are necessary to **bridge the valuation gap** between:
  - Sellers who want to realize the full value of their assets
  - Buyers who do not want to overpay for a drug in development
- Earn-outs can be based on:
  - development / regulatory / commercialization **milestones**
  - Sales **royalties**
  - Any combination of the above
- Pharma earn-out provisions are **unique due to the high failure rate** of product development

Phase	Discovery	Pre-clinical	Clinical development	Submission	Overall Success Rate
	51%	69%	12.8%	91%	4.1%

...that lead to real debates about appropriate "efforts standards"...

A seller who expects an earn-out will want to ensure that the buyer **expends appropriate energy developing the asset** to trigger the earn-out payment

Buyers will argue that they are interested in the success of the product and an efforts requirement is not required – but more often than not it will be included

When drafting an efforts requirement for a life sciences transaction, lawyers should bear in mind that:

- commonly used **"terms of art"** (e.g. best endeavors / reasonable endeavors etc) **should be avoided** as they mean different things in different jurisdictions
- each big **pharma company will have its own internal standards** and is likely to prefer that standard to a hypothetical industry norm
- it is not uncommon for companies to have **overlapping products in development**
- science (and medical needs) develop over time and **priorities may change** as a result
- development should have a set time frame and **an expiration date**

...and drafting needs to minimize the room for disagreement on key points

- Given real likelihood of milestones not being met, drafting should reflect that it is **best to reach agreement on points before a dispute has arisen**
- Earn-out provisions must address the following points:
  - Payment **triggers and mechanics must be objective** and clear
  - **Appropriate interim reporting** between Buyer and Seller to ensure no surprises at the end of the process
  - Choice of dispute mechanism should recognize the **potentially sensitive/confidential nature of facts** that may give rise to disagreements

Future trends in life sciences will affect the transactions landscape

- Continued **advances in science** – especially “personalized medicines” and other gene therapies
- Increased influence of **“digitization”**
  - Verily (aka Google) leading the charge
  - IT has the ability to change the way medicine is developed and sold
  - N.B. the divergent approach to development between the Tech sector and the life sciences sector
- Growing **importance of data**
  - Linked to digitization, growing ability to store and analyze data will aid innovation
  - Pharma companies holding historic clinical trials data hoping to re-use that information
  - N.B. complex data protection laws (especially cross border) that may slow the rate of progression
- On-going **pressure on drug pricing**
  - Generics makers will be especially affected
  - Increased emphasis on the biosimilars market (and away from small molecule generics)

Any questions?